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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,371	04/24/2001	Jean-Claude Thibault	64,149-099	5865

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EXAMINER

KENNY, STEPHEN

ART UNIT	PAPER NUMBER
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3726

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/841,371

Applicant(s)

THIBAUT ET AL.

Examiner

Stephen J Kenny

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 11-24 is/are allowed.
- 6) ☒ Claim(s) 1-3, 9 and 10 is/are rejected.
- 7) ☒ Claim(s) 4-8 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Applicant's Admitted Prior Art (AAPA) in view of Hellstrom et al. (WO 9739720).

Regarding claims 1 & 10, AAPA discloses a method of sealing a container with a closure, said container having an open end, filling said container with a substance & sealing by inserting an elastomeric stopper, said container comprising a radial rim portion surrounding said open end, a reduced diameter neck portion adjacent said rim portion and an enclosed container portion adjacent said neck portion, said method comprising: forming a closure having a cylindrical collar with an internal diameter slightly greater than the outside diameter of said rim portion of said container and integral rim portion; telescopically disposing said collar portion of said closure over said rim portion of said container with said radial rim portion of the closure overlying the rim portion of said container, and the cylindrical collar portion surrounding said rim of said container having a free end surrounding said reduced diameter neck portion of said container; and radially deforming the free end of the collar portion into the reduced diameter neck portion of the container beneath the rim portion, wherein the free end of the closure retains its shape following deformation to permanently retain the closure on said container and sealing said container open end (Applicant's page 2, lines 1-14).

AAPA does not disclose a closure formed from a plastic polymer.

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Hellstrom discloses a closure for a vial, which is made of plastic (page 13, line 16), wherein the free ends of the collar portion, or "Ferrule" (72 in Figure 1) securely seal the closure to the container. Note, in forming the secure seal, it is inherent that the plastic collar portion or "Ferrule" disclosed by Hellstrom is rigid enough to maintain its shape after deformation, as well as being resistant to creep. If the Ferrule were unable to resist creep and retain its shape the free ends of the closure would deflect outwards and release the compressive force that maintains the secure seal.

Furthermore, it is inherent that the plastic closure disclosed by Hellstrom be formed from a relatively soft (thereby allowing the piercing member to penetrate the closure membrane) and relatively hard polymer (thereby maintaining its shape as discussed above). Alternatively, AAPA discloses various polymers that are available, which comprise a relatively soft & relatively hard polymer (page 14, lines 15+).

Forming a closure of plastic as disclosed by Hellstrom is advantageous in that it is easier to deform, and is safer to handle than metal closures. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to form a vial closure as disclosed in AAPA with a plastic closure as taught by Hellstrom in order to realize the advantages discussed above.

Regarding claim 2, Hellstrom discloses an elastomeric stopper (20) in the container open end having a radial portion overlying the radial rim portion so said container, wherein the radial rim of the plastic closure compresses against the radial portion of the elastomeric stopper to seal the closure to the elastomeric stopper (page 13, lines 1-16). It is understood that the deformation of the free ends of the closure takes place substantially simultaneously to the compressing of the

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closure onto the elastomeric stopper. Such an order of operations is necessary to ensure a tight seal. If the deformation of the free ends of the closure were to occur, followed by the closure being compressed into the elastomeric stopper, then due to the displacement during compression, there would be a portion of the free end of the closure which extends below the radial rim of the container, yet isn't deformed or crimped against the container – therefore the resulting normal force exerted by the compressed elastomeric stopper would push the closure upwards, resulting in a faulty seal.

Regarding claim 3, Hellstrom disclose incrementally deforming the free end of the tubular collar portion into the reduced diameter neck portion (as illustrated by the varying degrees of deformation of portions 72 & 76 in Figures 2 & 4). In figure 1, portion 76 is shown to be deformed to a 90° angle with portion 72, whereas in Figure 4 corresponding portion 76 is deformed to an angle less than 90° - thereby illustrating incremental deformation.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over AAPA in view of Hellstrom as applied to claims 1, & 2 above, and further in view of Miller (US Patent No 4561555).

AAPA/Hellstrom disclose the instant invention as discussed above except for injection molding of the plastic closure.

Miller discloses injection molding of plastic fixtures (Column 2, line 25). Injection molding is a widely practiced process and is known to be able to mass-produce components at a low cost with precise tolerances and detailed, sharp geometry. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to form the plastic

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closure as modified by AAPA/Hellstrom by injection molding as taught by Miller, in order to realize the advantages discussed above.

Allowable Subject Matter

Claims 11-24 are allowed.

Claims 4-8 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 12/22/03 have been fully considered but they are not persuasive. Applicant has put forth the argument that the limitation of "a polymer alloy comprising a relatively malleable soft polymer and a relatively rigid polymer" distinguishes the claimed invention over the prior art. However as discussed above, in forming the secure seal, it is inherent that the plastic collar portion or "Ferrule" disclosed by Hellstrom is rigid enough to maintain its shape after deformation, as well as being resistant to creep. If the Ferrule were unable to resist creep and retain its shape the free ends of the closure would deflect outwards and release the compressive force that maintains the secure seal.

Furthermore, it is inherent that the plastic closure disclosed by Hellstrom be formed from a relatively soft (thereby allowing the piercing member to penetrate the closure membrane) and relatively hard polymer (thereby maintaining its shape as discussed above). Alternatively, AAPA discloses various polymers that are available, which comprise a relatively soft & relatively hard polymer (page 14, lines 15+).

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Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen J Kenny whose telephone number is 703-306-0359. The examiner can normally be reached on mon - fri 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Vo can be reached on 703-308-1789. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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